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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,633	07/10/2001	Robert John Macleod Wilson	117-347	5975

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NIXON & VANDERHYE, PC  
1100 N GLEBE ROAD  
8TH FLOOR  
ARLINGTON, VA 22201-4714

EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/18/2002

*22*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/787,633

Applicant(s)

WILSON ET AL.

Examiner

J. Eric Angell

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): The rejection of claims under 35 U.S.C 112, second paragraph only.

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 12 and 13.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other: \_\_\_\_\_

JEFFREY FREDMAN  
PRIMARY EXAMINER  
J. Eric Angell

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that the claims are drawn to a method of using an "old gene" (i.e. ycf24) based on the Applicants finding that the old gene (ycf24) is essential for the growth of organisms which cause disease. Applicants have disclosed three ycf24 genes (SEQ ID NO: 1-3) in the specification; however, the claims are not limited to the disclosed sequences and encompass sequences for which no written description is provided in the specification. The claimed genus of ycf24 genes encompasses every possible mutation or variation of a ycf24 gene that would confer growth to an organism which causes disease. As mentioned in the previous Office Action, a representative number of species of "ycf24 genes" must be described such that one of skill in the art would recognize that the Applicant was in possession of the necessary common attributes or features of the elements possessed by all members of the genus, in view of the species disclosed. The specification only discloses three sequences of ycf24 genes. The specification does not indicate any common attributes or features of the disclosed sequences which are possessed by all members of the genus of ycf24 genes. There is no disclosure indicating which sequences are essential for conferring growth functions to all species of ycf24 genes. Without a clear disclosure of which sequences are essential for the growth function of all ycf24 genes and which sequences are not essential, one of skill in the art would not be able to recognize that the Applicants were in possession of the necessary (i.e. essential) common attributes or features possessed by all members of this genus. Therefore, the specification does not contain the required written description of the genus of ycf24 genes encompassed by the claims.

Applicants argue that the claims are not drawn to new genes, but rather to a method of using an "old gene". In response, it is pointed out that the claims are drawn to a method of using any ycf24 gene, including "old" ycf24 genes as well as any yet-to-be-identified ycf24 genes.

In response to the applicants assertion that including the hundreds of millions of different sequences encompassed by the claims in the specification would not be concise, it is noted that the written description guidelines do not require that every possible species be disclosed, only that a description adequate to indicate the possession of the necessary common attributes/features possessed by all members of the genus. Here, an indication of the sequences of ycf24 genes that are necessary (i.e. essential) for conferring growth functions would suffice. However, the specification does not indicate which sequences of the ycf24 genes are necessary/essential for conferring growth and which sequences are not essential.

Applicants also assert that the facts of the cited cases (Vas-Cath vs. Mahurkar and The Regents of the University of California vs. Eli Lilly) are fundamentally different from the facts of the present case. Applicants point out that the cited cases were drawn to new DNA molecules, while the present case does not claim a new DNA molecule. In response, it is pointed out that 1) the written description requirements are not different for method claims; 2) the instant claims encompass methods of using all species of ycf24 genes, including any "new" ycf24 species not yet identified; and 3) The ycf24 molecules at issue are in fact DNA sequences which comprise all possible variations and mutations of ycf24, issues that closely map the Lilly fact pattern. Therefore, the cited cases are relevant.

Therefore, the the specification does not contain the required written description for the genus of ycf24 genes encompassed by the claims and rejection is not withdrawn.

J. Eric Angell